

REMARKS

Reconsideration of the application and entry of the foregoing amendments are respectfully requested.

Claims 12 and 13 are pending. Claims 14-19 have been canceled, without prejudice.

The amendments are being made solely to advance prosecution of the application to allowance and do not constitute an acquiescence, abandonment or disclaimer with respect to any subject matter originally claimed. Applicants reserve the right to pursue excluded subject matter by way of one or more continuing applications.

Rejection of claims 12, 13 and 16-19 under 35 USC 112, first paragraph

The cancellation of claims 16-19 has rendered this rejection moot in respect of those claims.

As regards claim 12 (and dependent claim 13), the pending claims specify that the claimed method is for "screening" for a compound that inhibits growth of an organism comprising the *ycf24* gene as opposed to "identifying" such a compound. In addition, the claims to refer to a positive result "suggesting" that the compound "may" have inhibiting activity instead of "being indicative" that the compound has such activity. The "screening" and "suggesting" language has been approved by the USPTO in, for example, US Patent No. 6,268,160 (which has one inventor in common with the present application), a copy of which is attached for the Examiner's convenience.

The pending claims are believed to satisfy the requirements of 35 USC 112, first paragraph; the specification is believed to contain a description that is more than adequate to enable a skilled person to perform the claimed method.

The physical steps required to perform the claimed method are relatively simple and are certainly within the ability of a person skilled in the art. All that the ordinarily skilled person has to do is contact a test compound with the *ycf24* gene product and determine whether the compound binds to the product. Methods of determining whether such binding is occurring are described in detail in the specification - see e.g. pages 6, line 22 to page 9, line 3. These methods rely on essentially standard assay techniques that can be performed as a matter of routine by the ordinarily skilled person, such as band shift assays and competitive binding assays.

The Examiner essentially argues that a positive result in the claimed method, i.e. binding to or inhibition of the *ycf24* gene product, is not adequately predictive that a compound inhibits growth of an organism containing the gene.

Applicants are not claiming however that any compound identified by the method of the invention will definitely have growth inhibition activity. What Applicants are claiming is that a positive result in the method suggests that the compound may have growth inhibition activity. The claimed method is intended to be used, for example, as a first-cut screening method to identify candidate compounds which can be studied further, not to necessarily show definitely that a compound is useful in *in vivo* therapy. Such screening methods are widely used in the art to identify candidate drugs.

Applicants believe that the specification does provide sufficient information to justify their claim that binding to or inhibition of the *ycf24* gene product is suggestive that the compound may be able to inhibit growth of an organism containing the gene. For

example, experiments described in the specification show that the inventors disrupted *ycf24* in both *Synechocystis* and *E. coli*, and found that disruption of all the copies of the *ycf24* gene in these organisms was lethal. Disruption of some of the copies of *ycf24* was found to give a 'ragged' phenotype in *Synechocystis* and appeared to cause a delay in or interfere in the process of septation during cell division. Furthermore, over-expression of *ycf24* was found to cause aberrant cell division in *E.coli*. Thus, the experiments described in the application show that *ycf24* is an essential gene.

In light of this showing, it is entirely reasonable for Applicants to claim that a positive result in the claimed method suggests that the compound tested may have growth inhibition activity.

In the Official Action, the Examiner appears to be drawing a distinction between compounds which bind to the *ycf24* gene product and those which inhibit the product. The Examiner stated that "a compound that binds to the *ycf24* "gene product" would not necessarily be an inhibitor of growth because there is no correlation between binding to the *ycf24* "gene product" and inhibition of growth" (Official Action of January 14, 2002, page 3, lines 3-6). Applicants respectfully submit that this statement is misplaced for two reasons.

Firstly, Applicants are not now claiming that a compound which binds to the *ycf24* gene product "necessarily" inhibits growth. On the contrary, as emphasised above, Applicants are claiming that binding suggests that the compound tested may have growth inhibition activity.

Secondly, it is entirely reasonable to assume there is a correlation between binding to the *ycf24* gene product and inhibition of growth. The correlation may not be 100%; i.e. it may be that less than 100% of compounds which bind to the gene product

also inhibit growth. However, there is still a sufficient correlation to suggest that a compound which binds to the *ycf24* gene product may inhibit growth. Binding is a necessary prerequisite to inhibition, and a binding assay of the type envisaged by the claims could be very valuable in providing a first cut of compounds for further investigation. The application contains more than sufficient information to enable an ordinarily skilled person to perform such a binding assay and come to a reasonable conclusion that a compound which gives a positive result in the assay may be a growth inhibitor.

The pending claims are supported by an enabling disclosure which adequately describes the claimed invention.

Rejection of claims 18 and 19 under 35 USC 112, second paragraph

This rejection has been rendered moot by the cancellation of claims 18 and 19.

Sequence compliance

Applicants have complied with the Examiner's request by way of the Amendment filed on January 24, 2002. The Amendment filed January 24, 2002 was not submitted in response to the Official Action of January 14, 2002, as indicated on page 3, in the Remarks, of the Amendment filed January 24, 2002. Nothing further is believed to be required in response to the communication of February 20, 2002, (Paper No. 13) however the Examiner is requested to advise the undersigned if otherwise.

WILSON et al
Serial No. 09/787,633

Return of an initialed copy of the PTO 1440 Form filed with the Information Disclosure Statement filed March 21, 2001, pursuant to MPEP § 609, is requested

Rejection of claims 16 and 17 under 35 USC 102 based on "a public use or sale of the invention"

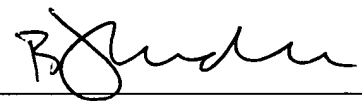
This rejection has been rendered moot by the cancellation of claims 16 and 17.

Return of an initialed copy of the PTO 1449 Form filed with the Information Disclosure Statement filed March 21, 2001, pursuant to MPEP § 609

It is respectfully submitted that the application is in condition for allowance, and a notice to that effect is requested.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Add the Abstract attached on a separate sheet.

IN THE CLAIMS

12. (Amended) A method [of identifying] for screening for a compound that inhibits the growth of an organism comprising the *ycf24* gene, the method comprising

- (i) contacting a test compound with the *ycf 24* gene product, and
- (ii) determining whether the test compound inhibits the activity of or binds to the product, any such binding or inhibition [being indicative] suggesting that the compound may inhibit [inhibits] the growth of the organism.